Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Automated Non-invasive Nerve Conduction Testing

PRIOR AUTHORIZATION: Not Required

POLICY:
For Senior Care: When the member has a high (more than 80%) pre-test or a prior probability for having the diagnosis of Carpal Tunnel Syndrome, the NC-stat® System (alone) will be allowed, one service per arm, per patient, per lifetime using CPT code 95905. The diagnosis ICD-9 354.0 should be used. All other ICD-9 codes will be denied as not medically necessary.

For ALL other lines of business SWHP considers automated point-of-care nerve conduction testing to be experimental and investigational and NOT a covered benefit.

OVERVIEW:
Nerve conductions studies (NCS) and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the gold standard of electrodiagnostic testing. Portable devices have been developed to provide point-of-care nerve conductions studies. These devices have computational algorithms that are able to drive stimulus delivery, measure and analyze the response, and provide a report of study results. Automated nerve conduction could be used in various settings, including primary care, without the need for specialized training or equipment.

Several devices are now being marketed for point-of-care neural conduction testing.

- NeuroMetrix received specific clearance to market NC-stat® via the U.S. Food and Drug Administration’s (FDA) 510(k) process in 1998, listing as predicate devices the TECA® model-10 electromyograph and the NeurometerTM by Neurotron, which measures vibration threshold. The FDA-listed intended use was “to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.” In addition, the approved application stated, “The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.” NeuroMetrix subsequently received FDA clearance to market newer models with biosensors and engineering changes that enable the NC-stat to be used for motor and sensory nerves of the wrist (median and ulnar) and foot (peroneal, tibial, and sural). The intended use as listed on the 510(k) approval from 2006
(#K060584) is “to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.”

- The NeuMed® Brevio® Nerve Conduction Monitoring System by Neurotron Medical, Inc. received FDA 510(k) clearance in 2001 as a hand held automated device intended for measurement of nerve latency and amplitude in the diagnosis and monitoring of peripheral neuropathies.

- The Xlitek® NeuropathTM(Excel-Tech) received clearance for marketing through the FDA’s 510(k) process in 2006; the indications are the same as those for NC-stat®. The Neural-ScanTM NCS (Excite Medical) is a Class I diagnostic device (FDA clearance not usually required) that is being marketed “as part the [sic] neurological examination or for screening to detect peripheral neuropathies.”

Assessment of a diagnostic technology typically focuses on three parameters:

- technical performance;
- diagnostic performance (sensitivity, specificity, and positive and negative predictive value) in appropriate populations of patients; and
- demonstration that the diagnostic information can be used to improve patient outcomes.

Studies have been done which demonstrate some correlation of portable automated nerve conduction test results with standard testing; however, questions remain about the diagnostic performance and clinical utility (i.e., impact on outcomes) of point-of-care automated testing. Particularly needed are data on the sensitivity and specificity of automated nerve conduction tests performed by non-specialists at the point-of-care in comparison with the “gold standard” of laboratory NCS/EMG. One potential clinical use could be early identification of asymptomatic diabetic neuropathy to institute appropriate clinical management before the onset of ulcerations, but no studies have been identified that assessed the influence of point-of-care nerve conduction tests on clinical outcomes in this population. Overall, evidence remains insufficient to evaluate the effect of automated point-of-care nerve conduction tests on health outcomes.

MANDATES: None

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

| CPT Codes: | 95905 (for SeniorCare) |
| ICD9 codes: | 354.0 (for SeniorCare) |
| ICD10 | G56.00 – G56.02 Carpal tunnel syndrome (for SeniorCare) |

CMS: There are no NCDs. LCD L32723 applies and criteria included in policy.

POLICY HISTORY:

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<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>New</td>
<td>12/6/2010</td>
<td>New policy</td>
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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


19. CMS Local Coverage Determination (LCD): Nerve Conduction Studies and Electromyography (L32723). Jurisdiction: Texas. Revision Effective Date: For services performed on or after 08/01/2013.